IFDA
international foodservice distributors association

Government Relations / Educational Services

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Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Resources
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 02N-0278 – Comments On Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam:

The International Foodservice Distributors Association (IFDA) is pleased to submit comments to the Food and Drug Administration (FDA) on the agency's proposed rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5428 (Feb. 3, 2003) ("prior notice proposed rule" or "proposed rule"). The proposed rule is intended to implement Section 307 of the Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), 21 U.S.C. § 381(m).

IFDA is a trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 135 members include broadline and specialty foodservice distributors that supply food and related products to restaurants and institutions in the "food away from home" business. IFDA members operate more than 550 facilities, and sell more than $64 billion in food and related products to the fastest growing sector in the food industry. Formerly a division of Food Distributors International, IFDA was established as an independent trade association on January 1, 2003.

IFDA commends FDA for its serious efforts to promulgate the prior notice proposed rule. IFDA shares FDA's commitment to protecting the U.S. food supply from the threats of bioterrorism. Nevertheless, IFDA believes that in many significant ways, the prior notice proposed rule does not effect the intention of Congress when it enacted Section 307. IFDA fears that the breadth and complexity of the prior notice rule, if implemented without significant changes, will have severe consequences upon international trade and yet not succeed in increasing the security of imported foods and protecting U.S. citizens from the risk of bioterrorist attack through the foods we consume.

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IFDA joins in the comments of trade associations and other commentators to the extent they address the following:

- The failure of the prior notice proposed rule to coordinate with existing reporting systems, specifically those of the U.S. Customs Service (Customs) and FDA's own Operational and Administrative Systems for Import Support (OASIS);
- The way in which the prior notice proposed rule adopts a "one size fits all" solution that does not accommodate modes of transportation, different ports and import practices, and types of food;
- The understatement of the significant costs that will have to be incurred to comply with the prior notice rule;
- The long and fixed time period for filing the prior notice (noon of the day prior to entry) when a shorter, and rolling time frame of 4 or 8 hours prior to port entry will be less disruptive to trade;
- The unreasonable restrictions upon amendments to previously filed notices and required updates to changes in time of arrival;
- The exactitude of the information required that far exceeds what the Bioterrorism Act mandates; and
- The failure to provide for procedures for the handling of refused articles of food and rights to appeal of adverse determinations.

IFDA specifically addresses in more detail two of these points below.

## FDA'S PROPOSED RULE EXCEEDS ITS STATUTORY AUTHORITY

Section 307 of the Bioterrorism Act is, in truth, a very limited requirement.

> In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the

> manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food

Section 307, Bioterrorism Act, 21 U.S.C. § 381(m)(1). The prior notice proposed rule exceeds the requirements of this statute in at least three ways.

First, the statute requires that FDA consult the Secretary of the Treasury, in other words, Customs. Yet, there is no evidence of such consultation in the proposed rule. Instead, FDA imposes a whole new system of required disclosures that very nearly duplicate the existing information provided to Customs when an importing broker makes an entry of an imported food. IFDA understands that through the Automated Broker Interface (ABI), brokers use Custom's Automated Commercial System (ACS) for cargo release and, for FDA-regulated product, complete an additional screen of information on FDA's own electronic entry system – OASIS. Additionally, Customs has now instituted the Advanced Presentation of Vessel Cargo Manifest Customs (67 Fed. Reg. 51519), which requires notification to Customs of a vessel's manifest, 24 hours prior to loading.

These Customs systems cover almost all imported food and capture nearly all the information required by Section 307. Yet, instead of coordinating with these existing systems of notification, FDA proposes a new, untested, and highly complex additional system. In IFDA's view, FDA has failed, as required by Congress, to duly and properly consult with Customs to lessen the burdens upon trade while still achieving the inspection purposes of the Section 307.

Second, the statute requires only seven data elements:

- The article;
- The manufacturer;
- The shipper;
- If known within the time the notice is required to be provided, the grower of the article;
- The country from which the article originates;
- The country from which the article is shipped; and
- The anticipated port of entry.

21 U.S.C. § 381(m)(1). These seven items reflect the considered judgment of the Congress as to what information was reasonably necessary for FDA to carry out the limited function for which the prior notice was designed – identification of which articles of food to inspect.

Without any support in the language of the statute, or the legislative history, FDA assumes that these plain and simple requirements are but a starting point for what is ultimately an extremely broad and highly technical new reporting requirement. The prior notice proposed rule goes far, far beyond what Congress envisioned. The prior notice submission form comprises 5 pages in the Federal Register and requires hundreds of pieces of information, including complex alpha-numeric codes (such as FDA product identify codes and the to-be-created registration numbers), lot numbers, brand names, place, date, and time of Customs entry, place, date and time of actual entry, and phone numbers, addresses, fax numbers, emails, and information about the many parties to a single article of food's importation, including the filer, manufacturer, shipper, grower, consignee, importer, and owner. The proposed information requirements are far more onerous than what Congress deemed was necessary to achieve the narrow, inspection purposes Section 307.

The prior notice proposed rule goes far beyond what the Bioterrorism Act requires and far exceeds what is necessary to enable FDA to identify which articles of food offered for import should be inspected. If the Congress intended for FDA to expand so far beyond what is set forth in the statute, it would have stated something equivalent to: "and such other information as the Secretary deems necessary." Section 307 contains no such expansion of FDA's authority.

Third, the prior notice proposed rule is far more restrictive than the Bioterrorism Act envisions. For instance, as quoted above, "Nothing in this section may be construed as a limitation on the port of entry for an article of food." This language is intended to provide that a product will not be refused admission into the United States for inadequate prior notice solely because the product arrives, due to normal shipping circumstances, at a port different from that specified in the notice. See Statement of Congressman John Shimkus, Cong. Rec. E2389 (Dec. 20, 2001). The prior notice proposed rule does not provide for any such flexibility or recognition of the commercial realities that result in changes to port of arrival (as well as date and time of arrival).

## FDA MUST PROPOSE PROCEDURES AND ALLOW FOR ADMINISTRATIVE APPEAL OF AGENCY DECISIONS AND JUDICIAL REVIEW

Section 307 provides that if an article of food is being imported into the United States and notice in advance has not been provided, the article shall be held for proper notice or removed to secure storage. FDA states that it will provide a list of approved, secure storage facilities. 68 Fed. Reg. at 5431. The filer or carrier of the article must arrange for transportation and storage. Proposed 21 C.F.R. § 1.278(d). The article of food will be held at that location until FDA deems a submitted prior notice to be adequate. Proposed 21 C.F.R. § 1.278(e).

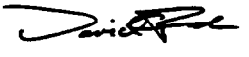
The lack of specification in proposed 21 C.F.R. § 1.278 is very troubling to IFDA and its members. There should be clear instructions to FDA personnel and to industry regarding the procedures that will be followed when food offered for import is held and removed to secure storage. When, how, and how soon will FDA notify the filing entity? How soon will FDA review a resubmitted prior notice? What procedures apply when the filer wishes to appeal an agency determination?

Practical considerations also need to be addressed. Doe FDA intend to staff ports on a 24/7 basis in order to clear products covered by an adequate prior notice? Is the agency's failure to appear at the port or to object at time of entry into the U.S. deemed to be acceptance of the prior notice? Other pressing and unresolved issues include what happens when there is some product that is deemed objectionable in a larger shipment, such as one item in a rail car, or the contents of an entire rail car on a freight train. How will FDA segregate product that is refused entry from that which may proceed? Must an entire truck unload? Will a rail car need to be uncoupled from a freight train? Will an entire shipping container be detained, or only the single article? Is there sufficient storage and staging capacity at ports to address these types of unloading and reloading issues? If the prior notice is deemed inadequate for technical reasons, such as typographical errors or minor changes to quantity, can corrections to the notice be made at the port?

IFDA notes that FDA seems to suggest that it is not required to provide for any review of its prior notice decisions because Section 307 did not explicitly provide for such review. IFDA respectfully disagrees. There is a strong presumption of review of agency decisions, both within the agency, and, once agency remedies are exhausted, in the courts. See e.g., Abbott Labs. v. Gardner, 387 U.S. 136 (1967)). FDA should identify an appeal mechanism in the event food products are held due to inadequate notice.

IFDA thanks FDA for this opportunity to comment.

Sincerely,



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